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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/574,333 | 07/21/2008 | Michael Karin | UCSD-10835 | 5879 |
| 7590 12/29/2010 | | | | |
| Meden & Carroll 101 Howard Street Suite 350 San Francisco, CA 94105 | | | EXAMINER QIAN, CELINE X | |
| | | | ART UNIT 1636 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,333

Applicant(s)

KARIN ET AL.

Examiner

CELINE X. QIAN

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2010.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) 1-6 and 15-19 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 7-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 30 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claims 1-19 are pending in the application. Claims 1-6, 15-19 are withdrawn from consideration. Claims 7-14 are currently under examination.

This Office Action is in response to the Amendment filed on 7/21/2010.

Response to Amendment

Acknowledgment is made of the submission of a new sequence listing, which is in compliance with 37 CFR 1.821-1.825.

The objections to the specification and claims 7-14 have been withdrawn in light of the amendment.

The rejection of claims 7-14 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of the amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 8, 10, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Saccani et al (Molecular Cell, 2003. Vol.11, pages 1563-1574).

Saccani et al. disclose a method that comprise the following steps: providing an isolated nucleotide sequence comprising SEQ ID NO: 57 that specifically binds to RelB Rel homology domain comprising SEQ ID NO: 62 (the ELC and MDC promoters comprises SEQ ID NO: 57), a polypeptide comprising RelB RHD (RelB comprises RelB RHD), and a compound (Ad

IkB α SR); contacting the nucleotide sequence with said polypeptide in the presence of said compound, detecting altered specific binding of said nucleotide sequence with said polypeptide (see pages 1568, bridging paragraph, and Figure 4 and legend). Saccani et al. further disclose that detecting binding of said nucleotide sequence to p65/RelA, and detecting binding of the polypeptide comprising RelB RHD to consensus κ B sequence, SEQ ID NO: 58 (see Figure 3 and legend, page 1567-1568, bridging paragraph). Saccani et al. also disclose that ELC is selectively activated by p52-RelB hetero-dimer (see page 1568, 1st col., 3rd paragraph, last 3 lines), it would have been inherent that the polypeptide DNA complex detected comprises said hetero-dimer. Although Saccani et al. do not teach the sequence of SEQ ID NOL 57, it is inherent that the promoter of ELC comprises said sequence because it specifically binds the RelB. Therefore, Saccani et al. disclose the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sacanni et al., in view of Toledano et al (PNAS, 1991. Vol. 88, pages 4328-4332).

The teaching of Sacanni et al. has been discussed above. However, Sacanni et al. do not teach contacting the polypeptide and the nucleotide sequence in vitro.

Toledano et al. teach method of detecting nucleotide and transcription factor binding complex in vitro. Toledano et al. teach modulating NF- κ B binding activity in vitro by oxidation and reduction (see abstract). Toledano et al. demonstrated DNA and the NF- κ B binding activity was detected by EMSA using germ translation product and the Ig κ B probe (see page 4330, 1st col).

It would have been obvious to an ordinary skill in the art that the binding of RelB-p52 dimer to nucleotide comprising the ELC promoter sequence as demonstrated by Sacanni et al. can also be detected to in vitro method as taught by Toledano et al. Methods of detecting DNA protein interaction between a transcription factor such as RelB-p52 and a promoter sequence in vitro are well known in the art as evidenced by the teaching of Toledano et al. The ordinary skill in the art would have used purified dimer and the promoter sequence to study the interaction in an in vitro setting to confirm the binding of the dimer to the specific sequence within the promoter. Combining prior art known methods to achieve a predictable result would have been within the capability of an ordinary artisan. Therefore, the claimed invention would have been prima facie obvious to an ordinary skill in the art at the time the invention was made.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joanne Hama can be reached on 571-272-2911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /
Primary Examiner, Art Unit 1636